



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/590,548

12/22/2006

Anders Carlsson

4528-0124PUS2

8478

2292 7590 04/30/2009
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

04/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/590,548	Applicant(s) CARLSSON ET AL.	
	Examiner IAN DANG	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 2-14, 16, 20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/20/2007, 12/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 15, and 19, in the reply filed on 03/23/2009 is acknowledged. The traversal is on the ground that

At page 2 of the response, Applicants argue that the Examiner has not provided sufficient evidence to support a finding of lack of unity. Moreover, the Examiner has not set forth sufficient evidence to establish that search and examination of all pending claims pose a serious burden.

Applicants' argument and response have been considered but are not found persuasive. The Examiner has provided the reference by Engstrom et al. (US Patent 5,151,272; published September 29, 1992; cited as reference AA in the IDS filed 12/13/2006) to indicate that the claimed invention does not have any special technical feature. More specifically, claim 1 is directed to a peptide-lipid complex in an aqueous solution, characterized in that the lipid is a bilayer-forming galactolipid material and that the weight ratio between the peptide and the galactolipid material is 1:5-1:50. Engstrom et al. (US Patent 5,151,272; published September 29, 1992; cited as reference AA in the IDS filed 12/13/2006) teach a composition comprising the peptide insulin (column 9, claim 16) and a lipid bilayer that has galactolipid material (column 9, claim 11) characterized by about 95% to 50% by weight (column 9, claim 18) corresponding to ratios of 1:2 to 1:20. The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Art Unit: 1647

In addition, the lack of unity does not require that the Examiner establishes that search and examination of all pending claims pose a serious burden

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-14, 16, 20, 22, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/23/2009.

Status of Application, Amendments and/or Claims

The amendment of 23 March 2009 has been entered in full. Claims 17 and 18 have been cancelled and claims 1, 13, 14, 16, and 19 have been amended.

Claims 1, 15, and 19 are under examination.

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1647

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Engstrom et al. (US Patent 5,151,272; published September 29, 1992; cited as reference AA in the IDS filed 12/13/2006).

The claimed invention is drawn to a peptide-lipid complex in an aqueous solution, wherein the lipid is a bilayer-forming galactolipid material and that the weight ratio between the peptide and the galactolipid material is 1:5-1:50.

The reference by Engstrom et al. teaches a composition comprising proteins that include insulin (column 8, claims 1, 6 and 8) and a lipid bilayer composed of a phospholipid material (column 8, claims 1 and 4) corresponding to a galactolipid material of the instant claim and characterized by about 95% to 50% by weight (column 8, claim 10) corresponding to ratios of 1:2 to 1:20 that are within the range disclosed in claim 1 of the instant application. The teaching of Engstrom et al. meets the limitations disclosed in claim 1.

In addition, the composition of Engstrom et al. is has the intended use for the controlled release of selected bioactive material *in vivo* (column 8, claim 1) corresponding to the medicament recited in claim 19 meeting the limitations of claim 19

Claims 1, 15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. (US Patent 6,306,433; filed 07/22/1998; issued 10/23/2001).

The reference by Andersson teaches a composition of lipid and a bioactive protein. The lipid is a glycolipid that is able to form a bilayer structure (column 6, lines 31-45) and the protein

Art Unit: 1647

is apolipoprotein (column 13, lines 13-14). Although the reference does not teach a bilayer-forming galactolipid material, the specification teaches that a glycolipid is a a bilayer-forming galactolipid material (see specification at page 5, lines 24-28) meeting the limitation recited in claim 1.

In addition, the reference teaches that the ratio between the peptide and the lipid is 1:4 (w/w) (or lipid to protein ratio about 4:1 (w/w)) (column 13, lines 26-29) that is included in the range of 1:5 to 1:50 correspond to the limitation of claim 1.

The teaching of Andersson meets the limitations of claim 1.

Futhermore, the reference by Andersson teaches that the peptide-lipid complex has a particle size ranging from 7 to about 25 nm (column 13, lines 46-47). Although the reference by Andersson does not teach a colloidal solution of the medicament, the composition would inherently be a colloidal solution because the peptide-lipid complex has the same elements as the one recited in claim 19 and also has the mean size of less than 100 nm. The teachings of Andersson meet the limitations of claim 15.

Finally, the reference by Andersson teaches that the peptide-lipid complex composition can be used in therapeutic and prophylactic treatment of disease (column 13, line 15) corresponding to the limitation of medicament meeting the limitation of claim 19.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
April 16, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647